

**REMARKS**

This Amendment is prepared in response to the first Office action mailed on 4 August 2006 (Paper No. 20060726).

**Listing of the Claims**

Pursuant to 37 CFR §121(c), the claim listing, including the text of the claims, will serve to replace all prior versions of the claims in the application.

**Status of the Claims**

Claims 1 through 18 are pending. Claims 1 through 6 are amended while claims 7 through 18 are newly presented.

**Claim Rejections - 35 U.S.C. § 102**

**A. Claims 1 through 3 are rejected under 35 U.S.C. §102(b) as being anticipated by Dicke, U.S. Patent No. 5,044,853.**

**A.1** As defined by independent claims 1, 7 and 13, Applicant teaches a helical implant formed with threads. The inclines, or in the terminology of threaded fasteners, the inclined flanks, of the threads are grooved with micro-patterns, in such a way that the cross-sections of the thread inclines bear the micro-patterns, in order to assist in increasing the contact area at the fixed portion and enhance the contact force.

A thorough reading of Dicke '853 discloses a thread-cutting screw in which the edge forming the screw tip is partially undulating. The undulating edge has recesses in the shape of a parabola formed in the area of the valleys of the thread edge on the face of

each flight. The recesses are asymmetrical so that the front flank face of the recess in the screw-in direction is steeper than the rear flank face in the screw-in direction, so that unscrewing the screw is more difficult than installation of the screw.

Pending claims 1, 7 and 13 are patentably distinguishable from Dicke '853.

**First**, the objects of the two inventions are different. The object of Dicke '853 is to make the unscrewing of the screw more difficult than the installation of the screw. In contradistinction, the structure of the insert defined by claims 1, 7 and 13 advantageously increases the contact area between the screw and the bone in which the screw is fixed.

**Second**, in Dicke '853, the undulating patterns are formed only at the edge of the flight that form the thread. Although the undulating edge has recesses interrupting the flank face of the thread, they are still confined around the thread tip, which is the outmost part of the thread, since the recesses are formed in the area of the valleys of the undulating patterns. See, for example, the following paragraphs in Dicke '853:

column 1, line 67, "Edge (5) of the flights that form thread (4) follows an undulating pattern";

column 2, lines 5-8, "In addition, recesses (6) are also formed in the area of the valleys (13) in the thread edge (5) at least on the face (10) of each flight facing the tip of the screw".

In the present application, however, the micro-patterns can be grooved not only close to the thread tip of the thread inclines, but also on the entire thread inclines, as shown in FIGs. 1 through 4.

**Third**, in Dicke '853, the undulating patterns have a smooth sequence of

elevations and indentations. See, for example, the following paragraph in Dicke '853:

column 1, line 68 and column 2, lines 1-2, "there is a smooth sequence of elevations (tips of the waves (12)) and indentations (valleys of the waves (13))".

And the recesses that are formed in the area of the valleys of the undulating patterns are also smooth, instead of having an edge. See, for example, the following paragraph in Dicke '853:

- column 2, claim 1, "the recesses (6) are in the shape of a parabola (9) and are asymmetrical";
- column 2, lines 15-16, "The transition (9) to the other flank face of thread flank (10) is designed as a parabola here";
- column 2, lines 24-27, "As shown by the figures, there is a fluid transition between recesses (6) and the remaining area of the thread flank, so there are no sharp edges and thus a cutting effect is prevented".

In claims 1, 7 and 13 however, the micro-patterns that are grooved on the thread inclines, or flanks, may be smooth, such as arcuate patterns, or have a edge, such as triangular and stepped or abruptly varying patterns. See, for example, FIGs. 1 through 4 and the following paragraphs in the present application:

page 5, lines 7-9, "Figs. 1 to 3 are a vertical sectional view of triangular, stepped and arcuate patterns formed on the thread inclines of the helical implant according to the present invention, respectively".

page 5, lines 31-34, "Without being limited to the shape and the number of the patterns, the micro- patterns on the helical implant according to the present invention have the triangular patterns 100a, the stepped patterns 100b and the arcuate patterns 100c and the like".

**Fourth**, in Dicke '853, the cross-sections of the thread inclines does not bear the undulating patterns which are formed on the edge of the flights. As is obvious from FIG.

1 through FIG. 3, the cross-sections of the areas of the thread inclines that correspond to the tips of the undulating patterns, are approximately straight lines, and the cross-sections of the areas of the thread inclines that correspond to the valleys of the undulating patterns, are approximately straight lines ended with curves, due to the recesses formed in around the thread tip. When the screw in Dicke '853 is fixed in an object, the surfaces of the recesses formed in the valleys do not contact the object, therefore the contact area between the screw and the object does not increase; instead, the contact area is decreased compare to the screw having the same outside diameter but without the recesses.

On the other hand, in the present application, the micro-patterns are grooved on the thread inclines, therefore the cross-sections of the thread inclines bear the micro-patterns. When the helical implant disclosed in the present application is fixed in an object, the entire surfaces of the thread inclines, i.e. the contours of the micro-patterns, contact the object. Therefore, the contact area between the screw and the object increases significantly.

**A.2** With respect to claims 1 and 3 (and, by extension, newly added claims 7 and 13), the Examiner alleges that Dicke '853 discloses “a helically threaded screw, wherein each of the threads has thread inclines comprising one or more recesses and protrusions” by citing “elevations (tips of the waves (12))” and “indentations (valleys of the waves (13))” in FIGs. 1-3 in Dicke '853. Applicant respectfully disagrees with this assertion by the Examiner.

**Firstly**, although Dicke '853 discloses undulating patterns with elevations and indentations, the undulating patterns are merely formed on the thread tip, i.e., the edge of the flight that form thread, instead of on the thread inclines. Therefore, the cross-sections of the thread inclines does not contain elevations and indentations. In the helical implant as claimed in claims 1 and 3 in the present invention, however, one or more recesses and protrusions are grooved on the thread inclines instead of only on the thread tip, in such a way that the cross-sections of the thread inclines bear the recesses and protrusions.

**Secondly**, although in Dicke '853, the undulating edge has recesses interrupting the flank face of the thread, since the recesses are formed in the area of the valleys of the undulating patterns, they are still confined around the thread tip. In the helical implant as claimed in claims 1 and 3 in the present invention, however, there is no limitations in the area at the thread inclines where the recesses and protrusions are grooved. In other words, the recesses and protrusions can be formed either on the entire thread inclines, or close to the thread tip, or close to the bottom of the thread, i.e., close to the screw shaft. Therefore, claims 1 and 3, together with newly presented claims 7 through 18, are patentably different from Dicke '853.

**A.3** With respect to claim 2, the Examiner alleges that Dicke '853 discloses "a polygonal cross-section opened at one side thereof" by citing FIGs. 2 and 3. Applicant respectfully disagrees with this assertion by the Examiner.

Firstly, "polygon" by definition is referred to as a closed plane figure bounded by

straight lines. A review of Dicke '853 discloses that the undulating patterns, as well as the recesses, are smooth. See, for example, the following paragraphs in Dicke '853:

column 1, line 68 and column 2, lines 1-2, "there is a smooth sequence of elevations (tips of the waves (12)) and indentations (valleys of the waves (13))";

column 2, lines 15-16, "The transition (9) to the other flank face of thread flank (10) is designed as a parabola here";

column 2, lines 24-27, "As shown by the figures, there is a fluid transition between recesses (6) and the remaining area of the thread flank, so there are no sharp edges and thus a cutting effect is prevented";

column 2, claim 1, "the recesses (6) are in the shape of a parabola (9) and are asymmetrical".

In the helical implant as defined by claim 2 in the present invention, however, the recesses grooved on the thread inclines may be smooth, such as arcuate patterns, or a polygon opened at one side, such as triangular and stepped patterns.

**Secondly**, as is obvious from FIG. 1 through FIG. 3 in Dicke '853, the cross-sections of the areas of the thread inclines that correspond to the tips of the undulating patterns, are straight lines, and the cross-section of the areas of the thread inclines that correspond to the valleys of the undulating patterns, are approximately straight lines ended with curves, due to the recesses formed in the valleys. In other words, some of the cross-sections of the thread inclines are straight lines with a curved pattern, while others do not bear any pattern at all. None of the cross-sections bear a polygonal pattern. In the helical implant as claimed in claim 2 in the present invention, however, the recesses are grooved on the thread inclines in such a way that the cross-sections of the thread inclines bear micro-patterns, such as polygons. Therefore, claim2 in the present application is

patentably distinguishable from Dicke '853.

**Claim Rejections - 35 U.S.C. § 103**

- B. Claims 4 through 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dicke in view of Hansson et al. (US 5,938,444).**

In support of this rejection, the Examiner states that:

Dicke discloses the helical screw as described above but fails to show both the recesses and protrusions shown have an arcuate cross section of identical curvature and length. Hansson, however, teaches a helically threaded implant which has threads that form recesses and protrusions that have an arcuate cross section of identical curvature and length (Figure 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make the recesses and protrusions of the present invention have arcuate cross sections of identical curvature and length in order to avoid, or at least minimize, stress-concentrations in the bone tissue around the threads as taught by Hansson. As to claims 5 and 6, Hanson [*sic*, "Hansson"] further discloses the use of micro-threads that have dimensions in the micrometer range (column 2, lines 24-28) in order for the threads to function as a screw, though not specifically a cross sectional area of 150µm. However, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make the implant with the recesses having such a cross sectional area since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

- B.1** A thorough reading of Hansson et al. '444 discloses an implant having a body with least one generally cylindrical part to be implanted into bone tissue. The cylindrical part is at least partly provided with threads having a height between 0.02mm and 0.20mm.

The pending claims are patentably distinguishable from Hansson et al. '444,

because in Hansson et al. '444, the micro-threads are formed on the envelope surface of the cylindrical body. See, for example, the following paragraph in Hansson et al. '444:

column 2, lines 24-27, "The envelope surface of the body 1 is provided with very small threads 2, herein called micro-threads since their dimensions are in the micrometer range. These threads will allow the implant to function as a screw".

There is no teaching or suggestion, however, that micro-patterns can be formed in the thread inclines of the micro-thread formed on the envelope surface of the body. On the other hand, the present invention discloses a helical implant constructed with threads and each of the threads has threads inclines grooved with micro-patterns. Therefore, the pending claims are patentably distinguishable from Hansson et al. '444,

**B.2** The Examiner alleges that Hansson et al. '444 teaches "a helically threaded implant which has threads that form recesses and protrusions that have an arcuate cross section of identical curvature and length" by citing FIG. 4. Applicant respectfully disagrees with this assertion by the Examiner.

Although Hansson et al. '444 teaches recesses and protrusions that have an arcuate cross-section of identical curvature and length, the recesses and protrusions are formed as threads, instead of being formed as micro-patterns on the thread inclines of the threads. In addition, although Dicke '853 teaches forming recesses, the recesses are formed merely around the thread tip. The recesses form curves at the cross-section of the thread inclines only at the areas of the thread inclines corresponding to the valleys of the



undulating patterns. There is no teaching or suggestion in the Examiner's combination of Hansson et al. '444 and Dicke '853 that arcuate patterns are formed on the thread inclines. Neither is there any proof that one having ordinary skill in the art at the time of Applicant's invention can make arcuate patterns at the cross-sections of the thread inclines. In the helical implant in the present invention, however, the arcuate patterns are grooved on the thread inclines and the cross-sections of the thread inclines reflect these arcuate patterns. Therefore, the pending claims are patentably distinguishable from the Examiner's combination of Hansson et al. '444 and Dicke '853.

**B.3** With respect to claims 5 and 6, the Examiner further alleges that Hansson et al. '444 discloses "the use of micro-threads that have dimensions in the micrometer range" by citing column 2, lines 24-28. Applicant respectfully disagrees with this assertion by the Examiner.

Although Hansson et al. '444 discloses that the dimensions of the micro-threads may be in the micrometer range, there is no disclosure that there are micro-patterns formed at the cross-sections of the thread inclines. In addition, Dicke '853 does not disclose preferred dimensions for the threads and recesses. Therefore, there is no teaching or suggestion in the Examiner's combination of Hansson et al. '444 and Dicke '853 that micro-patterns that have dimensions in the micrometer range are formed on the thread inclines, as is claimed in claims 5 and 6 in the present invention. Neither is there any proof that one having ordinary skill in the art at the time of Applicant's invention can

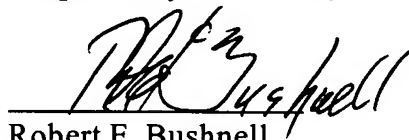
groove patterns in the micrometer range on the thread inclines. Therefore, the pending claims 5 and 6 are patentably distinguishable from the Examiner's combination of Hansson et al. '444 and Dicke '853.

**SUMMARY**

In view of the above, it is submitted that claims 1 through 6, and newly presented claims 7 through 18 of this application are in condition for allowance, and early issuance thereof is solicited. Should any questions remain unresolved, the Examiner is requested to telephone Applicant's attorney.

No fee is incurred by this Amendment.

Respectfully submitted,



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